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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/753,979 | 01/08/2004 | Martin Brady | 723.065US1 | 6449 |

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| EXAMINER |
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SCHELL, LAURA C

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| ART UNIT | PAPER NUMBER |
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3767

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/753,979 | BRADY ET AL. | |
| | Examiner | Art Unit | |
| | Laura C. Schell | 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: element 130 within Fig. 1 is not disclosed within the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "remotely detectable locator," "positioning system," and the "image-guided surgical workstation" in claims 9-11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 6 is objected to because of the following informalities: "with" should be changed to "within". Claim 20 is objected to because of the following informalities: "the" in "before the withdrawing" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8, 12, 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirimanne (US Patent No. 6,488,662). Sirimanne discloses a system comprising: a hollow tube (Fig. 1, 20), including a proximal end (Fig. 2, 58) and a distal end (56) and a lumen (Fig. 1, 20) extending there between (col. 7, lines 22-24), wherein the hollow tube is shaped and sized to permit insertion into a lumen of a flexible tubular infusion catheter (12; col. 4, lines 52-67), and wherein the hollow tube is stiffer than the infusion catheter (col. 7, lines 42-49) such that the hollow tube acts as a stylet for guiding the catheter through tissue to the target location. Sirimanne also discloses that the proximal end of the hollow tube is coupled to a fluid reservoir (60 and 62), the lumen of the hollow tube is filled with a fluid, and in which the proximal end of the hollow tube is configured to be closed and sealed (through valve 58) to retain the fluid within the lumen of the hollow tube (col. 7, lines 22-30). Sirimanne further discloses the flexible tubular infusion catheter (12) includes a proximal end (Fig. 1, 16) and a distal end (14) and a lumen extending there between, the lumen of the infusion catheter sized and shaped to permit insertion of the hollow tube therein (col. 4, lines 58-67). Sirimanne also discloses that the proximal end of the infusion catheter (16) sealingly engages around the hollow tube when a portion of the hollow tube is located within the lumen of the infusion catheter (element 18 provides the sealing engagement; col. 6, line 66 through col. 7, line 21). Sirimanne further discloses the lumen of the catheter having a diameter with two different values at different locations along the lumen of the catheter (Fig. 2, diameter at 28 and diameter at 22). Sirimanne also discloses a portion of the

inner diameter of the infusion catheter (52) at the proximal end (16) snugly seals to an outer diameter of the hollow tube to prevent air from passing there between (col. 6, line 66 through col. 7 line 21), as well as a distal portion of the inner diameter of the catheter (Fig. 1, 12) more loosely encircles the outer diameter of the hollow tube (20) than the proximal portion (at 52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne in view of Maginot et al. (US Patent No. 6,743,218). Sirimanne discloses the device substantially as claimed except for a clamp. Maginot, however, discloses a clamp (Fig. 3, 62 and 64) to be used at the proximal end of the catheter to prevent any fluid flow through the catheter system (col. 12, lines 12-18). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Sirimanne with the clamp as taught by Maginot in order to provide another mechanism in which stop the flow of fluid through the hollow tube.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne in view of Clayton et al. (US Patent No. 6,434,507). Sirimanne discloses the invention substantially as claimed including a remotely detectable locator (radio opaque marker 34 on the catheter), however this marker is not on the hollow tube; furthermore,

Sirimanne does not disclose a positioning system or image-guided surgical workstation. Clayton, however, discloses that a catheter with a remotely detectable locator (Fig. 2, 150) and includes a positioning system that permits location of the locator (col. 6, lines 17-38) and an image guided surgical workstation coupled to the positioning system (col. 5, line 58 through col. 6, line 16). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Sirimanne with the locator, positioning system and image-guided surgical workstation as taught by Clayton in order to provide a system that reliably can locate the position of the catheter in order to accurately perform the procedure, especially in light of the Sirimanne disclosing a locator on the catheter.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne in view of Hogan (US Patent No. 5,137,515). Sirimanne discloses the device substantially as claimed except for a cap and a plug at the end of the proximal tube. Hogan, however, discloses a cap (Fig. 1, 34) and plug (32) for the ends of a hollow tube (col. 3, lines 3-9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Sirimanne with the cap and plug as taught by Hogan in order to provide mechanisms to seal the end of the hollow tube.

Claim 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne in view of Shahbadian (US Patent No. 4,312,353). Sirimanne discloses the method substantially as claimed including: loading a hollow-tube with fluid (col. 8, lines 56-60), inserting the hollow tube into a lumen of a flexible infusion catheter to provide

Art Unit: 3767

enough stiffening to the catheter to guide the catheter (col. 8, lines 48-51), withdrawing the hollow tube from the catheter (col. 8, line 67 through col. 9, line 1), releasing the fluid from the stylet into the lumen of the catheter (col. 8, lines 56-64) and preventing the backflow of blood in the proximate end of the housing upon withdrawal of the hollow tube (col. 8, line 67 through col. 9, line 3). The cap (18) used to prevent the backflow of blood upon withdrawing the hollow tube provides a snug fit between the hollow tube and the catheter (col. 7, lines 2-19), and thus functionally would obviously prevent air from occupying the lumen of the catheter upon withdrawal of the hollow tube. Sirimanne further discloses infusing a fluid agent through the catheter after withdrawing the hollow tube (col. 9, lines 7-10). Sirimanne, however, does not disclose expressly directing the stylet and the catheter through tissue to the target. Shahbabian does disclose directing a catheter through brain tissue to a target location (col. 3, lines 19-24). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Sirimanne with the step of directing the catheter through brain tissue, in order to disclose a method in which a catheter is used to navigate human tissue for treatment purposes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

Art Unit: 3767

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LCS

LLS

Kevin E. Sirmons